IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TEVA PHARMACEUTICALS USA, INC., Plaintiff, v. AMGEN INC., Defendant.	CIVIL ACTION No. 2:09-cv-05675-SD
AMGEN INC., and AMGEN MANUFACTURING, LIMITED, Counterclaim Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS LTD., Counterclaim Defendants.	

AMGEN INC.'S ANSWER TO TEVA PHARMACEUTICALS USA, INC.'S COMPLAINT AND AMGEN INC. AND AMGEN MANUFACTURING, LIMITED'S COUNTERCLAIMS

Defendant Amgen Inc. ("Amgen") answers the allegations set forth in the Complaint for Declaratory Judgment of Patent Invalidity and Non-Infringement of Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva USA") as follows:

NATURE OF THE ACTION

1. Amgen admits that Teva USA's complaint purports to arise under the Declaratory Judgment Act and the United States Patent Law. While a case or controversy now exists between the parties, Amgen denies that a case or controversy existed under the Declaratory Judgment Act at the time Teva USA filed its Complaint.

2. Amgen admits that Teva USA's complaint purports to seek certain declarations

concerning U.S. Patent No. 5,580,755 ("the '755 patent") and U.S. Patent No. 5,582,823 ("the '823 patent") and attaches copies of the '755 and '823 patents as Exhibits 1 and 2 of the complaint.

THE PARTIES

3. Upon information and belief, Amgen admits the allegations in paragraph 3.

4. Amgen admits the allegations of paragraph 4.

JURISDICTION AND VENUE

5. Amgen admits that Teva USA's complaint purports to arise under the Declaratory Judgment Act and the United States Patent Law. While a case or controversy now exists between the parties, Amgen denies that a case or controversy existed under the Declaratory Judgment Act at the time Teva USA filed its Complaint.

6. Amgen admits that Teva USA's complaint purports to allege federal jurisdiction under 28 U.S.C. §§ 1331, 1338(a) and 2201(a). While a case or controversy now exists between the parties, Amgen denies that a case or controversy existed under the Declaratory Judgment Act at the time Teva USA filed its Complaint.

7. Amgen admits the allegations in paragraph 7.

8. Amgen admits the allegations in paragraph 8.

BACKGROUND

9. Amgen admits the allegations in paragraph 9.

10. Amgen admits that the approved indications for Neupogen® include reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with acute myeloid leukemia (AML); decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies

receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; reducing the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation; the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; and chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. Amgen denies the remainder of the allegations in paragraph 10.

11. Amgen admits that Neupogen® and its use are covered by U.S. Patents Nos. 4,810,642 ("the '643 patent"), 4,999,291 ("the '291 patent") and the '755 and '823 patents, and that the terms of the '643 and '291 patents have expired.

12. Amgen admits that the United States Patent and Trademark Office ("PTO") issued the '755 patent on December 3, 1996. Amgen admits that the '755 patent is titled "Human Pluripotent Granulocyte Colony-Stimulating Factor" and identifies Lawrence M. Souza as the inventor and Amgen as the assignee. Amgen admits that according to the current records of the PTO, the term of the '755 patent is presently set to expire on December 3, 2013. Amgen denies the remainder of the allegations in paragraph 12.

13. Amgen admits that the PTO issued the '823 patent on December 10, 1996. Amgen admits that the '823 patent is titled "Methods of Treating Bacterial Inflammation and Granulocytopoiesis by Administering Human Pluripotent Granulocyte Colony-Stimulating Factor" and identifies Lawrence M. Souza as the inventor and Amgen as the assignee. Amgen admits that according to the current records of the PTO, the term of the '823 patent is presently

set to expire on December 10, 2013. Amgen denies the remainder of the allegations in paragraph 13.

14. Amgen lacks knowledge and information sufficient to form a belief as to the truth of the allegations in paragraph 14 and therefore denies those allegations.

15. Upon information and belief, Amgen admits the allegations in paragraph 15.

16. Upon information and belief, Amgen admits the allegations in paragraph 16.

17. Amgen lacks knowledge and information sufficient to form a belief as to the truth of the allegations in paragraph 17 and therefore denies those allegations.

18. Amgen lacks knowledge and information sufficient to form a belief as to the truth of the allegations in paragraph 18 and therefore denies those allegations.

19. Amgen admits that the November 27, 1990 Los Angeles Times and January 26, 2007 Wall Street Journal Online published the words set forth in paragraph 19. Amgen otherwise denies the allegations in paragraph 19.

20. Amgen admits that it asserted its patents and sought declaratory judgment against Hoechst Marion Roussel and Hoffman-La Roche in the cases set forth in paragraph 20. Amgen otherwise denies the allegations in paragraph 20.

21. Amgen admits that Teva USA has stated that, once Teva's BLA is approved by the FDA, Teva USA intends to sell its Filgrastim product in the United States without a license from Amgen and prior to the expiry of Amgen's '755 and '823 patents. Amgen further admits that it is expected that Teva USA's product, if approved, would compete with Amgen's NEUPOGEN® product. Amgen otherwise lacks knowledge and information sufficient to form a belief as to the truth of the allegations in paragraph 21 and therefore denies those allegations

22. Amgen denies the allegations in paragraph 22.

TEVA USA'S FIRST CLAIM FOR RELIEF

23. Amgen incorporates its responses to the allegations of paragraphs 1 through 22 as if fully set forth herein.

24. Amgen denies the allegation in paragraph 24.

25. Amgen denies the allegation in paragraph 25.

TEVA USA'S SECOND CLAIM FOR RELIEF

26. Amgen incorporates its responses to the allegations of paragraphs 1 through 25 as if fully set forth herein.

27. Amgen denies the allegation in paragraph 27.

28. Amgen denies the allegation in paragraph 28.

TEVA USA'S PRAYER FOR RELIEF

29. Amgen incorporates its responses to the allegations in paragraphs 1 through 28 as if fully set forth herein.

A. Amgen denies that Teva USA is entitled to the relief it seeks in paragraph A.

B. Amgen denies that Teva USA is entitled to the relief it seeks in paragraph B.

C. Amgen denies that Teva USA is entitled to the relief it seeks in paragraph C.

D. Amgen denies that Teva USA is entitled to the relief it seeks in paragraph D.

E. Amgen denies that Teva USA is entitled to any relief at all for the allegations made in the complaint.

AMGEN'S COUNTERCLAIMS

Amgen Inc. and Amgen Manufacturing, Limited assert the following counterclaims against Teva Pharmaceuticals Ltd. and Teva Pharmaceuticals USA, Inc.:

THE PARTIES

1. Counterclaim-Plaintiff Amgen Inc. ("Amgen") is a corporation existing under the laws of the State of Delaware with its principal place of business in Thousand Oaks, California. Amgen discovers, develops, manufactures and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology and chemistry.

2. Counterclaim-Plaintiff Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico. AML manufactures and sells biologic medicines for human therapeutic uses.

3. Counterclaim-Defendant Teva Pharmaceuticals Ltd. ("Teva Ltd.") is a foreign corporation existing under the laws of Israel with its principal place of business in Netanya, Israel.

4. Counterclaim-Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

5. Teva USA is a wholly-owned subsidiary of Teva Ltd.

6. Counterclaim-Defendants Teva Ltd. and Teva USA are hereinafter referred to individually and collectively as "Teva."

JURISDICTION AND VENUE

7. This action involves Teva's announced plan to import and sell a product called NEUTROVAL™ containing recombinant methionyl human granulocyte colony-stimulating factor ("Filgrastim") well in advance of the expiry of two United States patents assigned to Amgen and thus arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331,

1338(a), 2201(a) and 2202.

8. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c), and (d), and 1400(b).

DR. SOUZA'S PIONEERING INVENTIONS

9. The patents at issue describe and claim the path-breaking inventions of an Amgen scientist, Dr. Lawrence M. Souza, relating to "human pluripotent granulocyte colony stimulating factor" ("G-CSF").

10. Natural forms of G-CSF are produced by animals (including humans) and stimulate the production of predominantly granulocytic white blood cells. Prior to Dr. Souza's path-breaking inventions, preparations containing G-CSF had been obtained from naturally-occurring sources, but these preparations did not enable skilled artisans to characterize the complete structure or activity of the human protein. Nor did they teach the gene sequence of human G-CSF, provide workable means to produce and obtain therapeutically useful quantities of recombinant G-CSF proteins, or permit the treatment of patients in need of G-CSF, such as cancer patients undergoing chemotherapy whose white blood cell levels have been suppressed by the chemotherapy they receive. Without therapeutically useful quantities of G-CSF, these immunocompromised patients, in some instances, would be unable to complete their cancer treatments because of infection.

11. Through Dr. Souza's path-breaking inventions, DNA molecules encoding G-CSF were purified and isolated, and recombinant methods were developed for producing isolated G-CSF in quantities sufficient for clinical testing and therapeutic use, enabling the treatment of a variety of medical disorders using G-CSF.

12. Recognizing the many different inventions made and taught by Dr. Souza, the

United States Patent Office ultimately issued multiple patents for his life-saving inventions. Two of Dr. Souza's inventions are described and claimed in the patents at issue here:

a. U.S. Patent No. 5,580,755 (the "'755 patent"), issued on December 3, 1996, claims human G-CSF polypeptides, specific analogs of those polypeptides, and compositions containing such polypeptide products. A true and correct copy of the '755 patent is attached hereto as Exhibit 1.

b. U.S. Patent No. 5,582,823 (the "'823 patent"), issued on December 10, 1996, claims, among other things, methods of treating patients by administering G-CSF polypeptides or specific analogs of those polypeptides. A true and correct copy of the '823 patent is attached hereto as Exhibit 2.

13. Dr. Souza assigned all of his rights in and to the '755 and '823 patents to Amgen and Amgen is the owner of the '755 and '823 patents.

14. Based on Dr. Souza's inventions, Amgen developed a therapeutic product called NEUPOGEN®. Since its approval by the FDA in 1991, NEUPOGEN® has been administered to patients to stimulate white blood cell production, thereby reducing the risk of infection to patients undergoing treatments like chemotherapy. The active ingredient in NEUPOGEN® is a form of G-CSF known as recombinant methionyl human granulocyte colony-stimulating factor ("Filgrastim"). Filgrastim falls within the scope of claim 1 of the '755 patent.

15. Amgen also has developed another therapeutic product called Neulasta® based upon Filgrastim. The active ingredient in Neulasta® is pegfilgrastim which is a covalent conjugate of Filgrastim and monomethoxypolyethylene glycol. Neulasta® was approved by the FDA in 2002. It has a longer half-life and requires less frequent dosing than Neupogen®. Pegfilgrastim and its use fall within the scope of one or more claims of the '755 patent and '823

patent.

16. Amgen has granted AML an exclusive license under the '755 and '823 patents, including the exclusive right to make and sell NEUPOGEN® and Neulasta® in the United States for all human therapeutic uses.

TEVA'S INFRINGING PRODUCT AND USES

17. On information and belief, Teva has developed a product called NEUTROVAL™ containing Filgrastim that it intends to import and sell for use in the United States. On information and belief, Teva's Filgrastim product is manufactured in Lithuania. That product is then sent to Mexico to be filled and finished.

18. On information and belief, the Filgrastim product for which Teva seeks FDA approval to market in the United States under the proposed name NEUTROVAL™ is the same Filgrastim product that Teva sells in Europe under the trademark TevaGrastim®. In a February 21, 2008 press release, Teva characterized its Filgrastim product as "biosimilar" to Amgen's "innovator product," NEUPOGEN®. In a January 12, 2009 presentation, Teva characterized its Filgrastim product as a "biogeneric."

19. On information and belief, Teva's Filgrastim product contains recombinant methionyl human granulocyte colony-stimulating factor.

20. On information and belief, Teva's Filgrastim product contains a polypeptide having an amino acid sequence corresponding to positions -1 to +174 recited in claim 1 of the '755 patent.

21. On information and belief, Teva's Filgrastim product can be used to treat a mammal for bacterial inflammation. On information and belief, Teva's Filgrastim product can be used to provide granulocytopoietic therapy to a mammal.

22. Teva has knowledge of the '755 and '823 patents. Despite this knowledge, Teva has stated that, upon FDA approval, it intends to sell its Filgrastim product in the United States prior to the expiration of the '755 and '823 patent without a license from Amgen.

23. Teva has announced that it filed a Biologics License Application ("BLA") with the United States Food and Drug Administration ("FDA") on November 30, 2009 seeking approval to market and sell its Filgrastim product in the United States under the proposed name NEUTROVAL™. Teva has stated that its BLA seeks approval to market and sell its Filgrastim product in the United States for the reduction in the duration of neutropenia (depleted levels of certain white blood cells) and the incidence of febrile neutropenia in patients treated with established cytoxic chemotherapy for malignancy and for the reduction in the duration of neutropenia in patients that undergo myeloablative therapy followed by bone marrow transplantation.

24. On information and belief, Teva has taken other steps in preparation for importing, marketing, and selling its Filgrastim product in the United States. These steps include hiring or attempting to hire employees to support the marketing and sale of its Filgrastim product in the United States.

FDA'S REVIEW PROCESS

25. On information and belief, the timeframe by which the FDA will review Teva's November 30, 2009 BLA is governed by the Prescription Drug User Fee Act (21 U.S.C. § 301 et seq.). FDA seeks to complete its final review of all such applications within 10 months of an application's accepted filing date. FDA is therefore likely to take final action on Teva's November 30, 2009 BLA before year-end 2010. Teva has stated that it believes the approval of its BLA will come well in advance of the expiry of the '755 and '823 patents.

FIRST CAUSE OF ACTION
(DECLARATORY JUDGMENT OF INFRINGEMENT)

26. Amgen and AML re-allege and incorporate by reference the allegations in paragraphs 1 through 25 above.

27. Teva has been and is making meaningful preparations to market and sell Filgrastim in the United States.

28. Teva has stated that, following FDA approval, Teva intends to sell its Filgrastim product in the United States prior to the expiration of the '755 and '823 patents without license from Amgen.

29. Teva's importation, sale, offer to sell, and/or use of its Filgrastim product in the United States will imminently infringe, directly and indirectly, literally or under the doctrine of equivalents, the claims of the '755 and '823 patents.

30. A real, immediate, and substantial controversy now exists between the parties concerning Teva's infringement of the '755 and '823 patents.

31. Amgen and AML seek a judicial determination and declaration that, upon FDA approval, Teva will infringe, either literally or under the doctrine of equivalents, one or more claims of the '755 and/or '823 patents by making, importing, using, selling, and/or offering for sale products containing Filgrastim. To the extent that Teva engages in such acts prior to the final adjudication of this matter, Amgen and AML seek a judicial determination and declaration that such acts infringe, literally or under the doctrine of equivalents, one or more claims of the '755 and/or '823 patents. Such a determination and declaration is necessary and appropriate at this time in order that the parties may ascertain their respective rights and duties.

32. Absent injunctive relief in advance of Teva's importation, sale, or offer to sell its Filgrastim product in the United States, Amgen and AML will suffer irreparable harm for which

there is no adequate legal remedy. The balance of hardships and the public interest support granting injunctive relief in favor of Amgen and AML to stop Teva's imminent infringement.

PRAYER FOR RELIEF

Wherefore, Amgen and AML request that the Court enter judgment in its favor and against Teva as follows:

a. Declaring that the '755 and/or '823 patents are currently infringed or will be infringed by Teva's importation, use, offer for sale, and/or sale in the United States of products containing Filgrastim;

b. Enjoining Teva from making, importing, using, selling or offering to sell products containing Filgrastim in the United States for the life of the '755 and/or '823 patents;

c. Accounting for all products containing Filgrastim that Teva has made, imported, used, sold, or offered to sell in the United States;

d. To the extent that Teva makes, uses, offers for sale, sells, or imports products containing Filgrastim prior to final adjudication of this matter, awarding Amgen and AML damages in the amount not less than Amgen and AML's lost profits;

e. Awarding Amgen its costs and expenses of suit;

f. Granting Amgen such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Amgen and AML demand a trial by jury on all issues so triable.

Dated: January 15, 2010

By: */s/ David J. Wolfsohn*

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CERTIFICATE OF SERVICE

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